

**REMARKS**

This is a Response to the Office Action dated September 22, 2006. Claims 25-33 are pending in this application. The Examiner has rejected Claims 25-33. Claim 32 has been amended.

**35 USC § 103(a) rejection of claims 25-33**

The Examiner has rejected claims 25-33 under 35 USC § 103(a) as being unpatentable over Yang et al. (WO 01/01890 A1) ("Yang"). Applicants respectfully disagree.

Claim 25 recites "a coating layer disposed on" a "stent body" and "polymeric particles containing a therapeutic substance embedded within the coating layer." Claim 32 recites an "implantable substrate and a coating" such that "the coating includes particles of a polymeric material having a therapeutic substance added thereto." Yang fail to teach or suggest the above limitations of claims 25 and 32.

As indicated by the Examiner, Yang disclose a stent with "a coating disposed over at least a portion of the body, and an active agent releasably dispersed in at least part or portion of the coating." The Examiner further states that "the stent can be coated by spraying the stent with a solution or dispersion of polymer, active agent and solvent. The solvent can be evaporated, leaving a coating of polymer and active agent. The active agent can be dissolved and/or dispersed in the polymer. In some embodiments, the co-polymer can be extruded over the stent body."

Yang do not teach, expressly or inherently, polymeric particles containing a therapeutic substance embedded in a coating. There is no indication by Yang or the Examiner that the surface treatment techniques cited on p. 7 of Yang would result in the formation of polymer particles containing a therapeutic agent embedded in the coating. In particular, there is no teaching or suggestion that evaporation of an applied mixture of solvent, polymer, and a therapeutic agent results in a coating including polymeric particles containing the therapeutic agent embedded in the coating.

Although Yang teaches that active agent can be dispersed in the polymer of a coating, there is no express or inherent teaching that the dispersed active agent is within polymeric particles. Additionally, although Yang teaches that the coating can include a blend of first and

second co-polymers, there is no teaching or suggestion that the blend includes particles of one polymer dispersed within the other.

Furthermore, the Examiner has provided no motivation for modifying the teachings of Yang so that it teaches the above-mentioned claim limitations. MPEP 2143 states that one of the requirements of a *prima facie* case of obviousness is that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Another criteria for a *prima facie* case is that the combined references teach or a modified prior art reference teaches or suggests all claim limitations. MPEP 2143.

The Examiner states that “given the explicit teachings of Yang *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.” The Examiner states a conclusion without providing any support or argument for meeting the requirements stated above for a *prima facie* case of obviousness. As indicated above, the “explicit teachings” of Yang do not teach all the claim limitations. Furthermore, the Examiner has not provided a suggestion or motivation contained either in another reference(s) or in the knowledge generally available to one of ordinary skill in the art to modify Yang so that it teaches the above-mentioned claim limitations. Therefore, the Examiner’s remarks do not meet either of the requirements for a *prima facie* case of obviousness above.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claims 25 and 32 are allowable. Claims 26-31 depend from claim 25 and are allowable for at least the same reason that claim 25 is allowable. Claim 33 depends from claim 32 and is allowable for at least the same reason that claim 32 is allowable. Applicant respectfully requests removal of the rejections.

### **35 USC § 103(a) rejection of claims 25, 26, 28, 29, 30 and 32**

The Examiner has rejected claims 25, 26, 28, 29, 30 and 32 under 35 USC § 103(a) as being unpatentable over Berg *et al.* (U.S. Patent No. 5,464,650) (“Berg”). Applicants respectfully disagree.

The Examiner states that Berg “teach a drug-containing expandable stent and method for making an intravascular stent by applying to the body of a stent solution, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent.” The Examiner further states that “the method can be applied by immersing the stent into the solution or by spraying the solution onto the stent (col. 2, lines 40-44). Processes for preparing the coated stent are also disclosed on column 3, line 52 - col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared.”

Berg do not teach, expressly or inherently, polymeric particles containing a therapeutic substance embedded in a coating. Berg teach preparing a solution with a “polymer dissolved in a solvent” (col. 3, line 54), applying the solution to a stent, and then allowing the solution to evaporate. (col. 4, lines 19-20). There is no teaching or suggestion of applying a solution of polymeric particles to a stent.

Berg do teach coating a stent with a solution containing solvent with a therapeutic substance “dispersed in fine particles.” (col. 3, line 64) In addition, Example 2 of Berg teaches dipping a stent in a “solution with suspended particles of dexamethasone.” (col. 5, lines 60-61) However, there is no indication by Berg or the Examiner that a coating with polymeric particles containing therapeutic agent embedded in the coating is formed. Thus, there is no express or inherent teaching or suggestion that the dispersed therapeutic agent is within polymer particles.

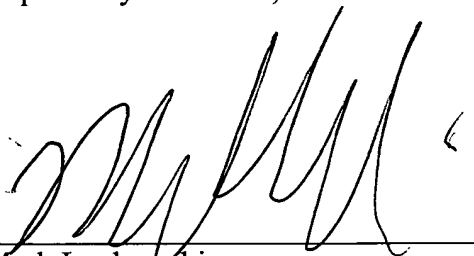
As with Yang, the Examiner states a conclusion of a *prima facie* case of obvious without providing any support or argument for it. The “explicit teachings” of Berg do not teach all the claim limitations. Furthermore, the Examiner has provided no motivation or suggestion to modify Berg so that it teaches the above-mentioned claim limitations.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claims 25 and 32 are allowable. Claims 26, 28, 29, and 30 depend from claim 25 and are allowable for at least the same reason that claim 25 is allowable. Applicant respectfully requests removal of the rejections.

**CONCLUSION**

Removal of the rejection and allowance of the claims is respectfully requested. Should the Examiner have any questions or concerns, the Examiner is invited to call the undersigned attorney of record.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark Lupkowski', written over a horizontal line.

Mark Lupkowski  
Attorney for Applicants  
Reg. No. 49,010

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Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0297  
mlupkowski@ssd.com